

### **REMARKS**

In this Response, Applicant amends claim 13, and addresses the Examiner's objections and rejections. Support for the amendment to claim 13 can be found in the specification and the claims as filed, e.g., paragraph [0046] of the application publication and the original claim 13 (before the preliminary amendment).

The amendment to the claims are being made solely to expedite prosecution and do not constitute an acquiescence to any of the Examiner's objections or rejections. Applicant's silence with regard to the Examiner's rejections of the dependent claims constitutes a recognition by the Applicant that the rejections are moot based on Applicant's amendment and/or remarks relative to the independent claim from which the dependent claims depend. Applicant reserves the option to further prosecute the same or similar claims in the present or a subsequent application.

Upon entry of the amendments, claims 1-20 are pending. The amendments do not constitute new matter. Reconsideration of the application in view of the amendment and the following remarks is respectfully requested.

#### **I. Information Disclosure Statement**

The Examiner states that a copy of original document JP 08-056562A was not received and only English language abstract was received. However, the Examiner indicates that he did obtain the original JP 08-056562A as well as a machine translation thereof. Indeed, the Examiner uses the English Abstract and the machine translation to reject claims 17 and 20 in the Office Action. As such, Applicant believes the submission of the original document JP 08-056562A is no longer necessary.

#### **II. Claim Objection**

Claim 13 is objected to for being a substantial duplicate of claim 12.

Applicant has currently amended claim 13 to recite "A method for increasing vitality, comprising ..." The amended claim 13 substantially differs from claim 12. Therefore, Applicant respectfully requests that the objection be withdrawn.

### III. Rejections under 35 U.S.C. § 103(a)

All of the pending claims are rejected under 35 U.S.C. § 103(a) over a few cited references alone or in combination of one another. Applicant respectfully traverses all these rejection. To reject claims in an application under Section 103, an Examiner must establish a *prima facie* case of obviousness. Under the Supreme Court's guidelines enunciated in *Graham v. John Deere*, 383 U.S. 1, 17 (1966), and reaffirmed in *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (2007), to establish a *prima facie* case of obviousness, the Examiner has an obligation to construe the scope of the prior art, identify the differences between the claims and the prior art, and ascertain the level of skills of an ordinary person in the art. Further, as the Board of Patent Appeal and Interferences (BPAI) has recently opined, a proper obviousness determination requires that the Examiner make "a searching comparison of the claimed invention – *including all its limitations* – with the teaching of the prior art." See *In re Wada and Murphy*, 2008 WL 142652, (Bd. Pat. App. & Interf.), January 14, 2008, APPEAL 2007-3733 (emphasis in original). In addition, objective evidence (secondary considerations) remain as an integral part of the obviousness inquiry, and can rebut a *prima facie* obviousness determination by the Examiner.

In the following, Applicants address these obviousness rejections separately and in the order as they appear in the Office Action.

(A) Rejections of claims 1-3, 5-7, 15-16, and 18-19 over U.S. Patent No. 4,089,985 to Wolff ("Wolff") (Office Action, pages 3-6).

Applicant's independent claim 1, as filed, recites the following:

1. A method for preparing a puree preparation from *Carica papaya* fruits, comprising:
  - cooking the *Carica papaya* fruits in an aqueous medium for at least 30 minutes at normal pressure, wherein the volume of the aqueous medium is at least twice of the water content of the fruits;
  - cooling the cooked *Carica papaya* fruits for a period of at least 30 minutes in an oxygen-containing atmosphere; and
  - optionally homogenizing the cooled *Carica papaya* fruits by at least one of crushing, mixing and straining the mixture.

Wolff does not disclose or suggest claim 1. As stated in the Summary of the Invention, the primary object of Wolff is "the production of a fruit juice from fresh papaya, which *fruit juice will not have a bitter taste or smell, will have a pleasant taste typical of papaya ...*"

(emphasis added). See col. 2, lines 5-8. To this end, Wolff discloses a method for producing such a papaya juice product, including the following steps

6. The material is blended for at least ten minutes with the blender impeller cutter blades 3 rotated at a sufficiently high speed to add considerable heat by mechanical action to the material and simultaneously homogenize the material until the temperature of the material so processed *is raised to about 195° F (91° C)*. This high speed blending for at least ten minutes insures that all the papaya meat is broken down into fine particles during this phase of the process.

7. The high speed blending is continued for *an additional period of at least 3 minutes* with the blender covered, the temperature of the material being thus held at or above 195° F (91° C) while being further homogenized.

See col. 3, lines 18-31. However, Wolff does not disclose or suggest *cooking* papaya fruits for *at least 30 minutes*, or *cooling said cooked papaya fruits for a period of at least 30 minutes in an oxygen containing atmosphere*. Therefore, it cannot render the independent claim 1 obvious.

In making this rejection, the Examiner relies on a rationale that varying the temperature of cooking papaya is well within a person of ordinary skill in the art based on the teaching of Wolff. Applicant disagrees with this reasoning, noting that Wolff only teaches blending the papaya meat (optionally with water) to raise the temperature *to* about 91 °C, and then continuing the blending for additional 3 minutes. As such, the total period of time the papaya in Wolff is subjected to the “cooking” temperature in Wolff is significantly below 30 minutes as recited in claim 1. Contrary to the Examiner’s assertion, to extend this period of time to at least 30 minutes is not obvious, as a person skilled in the art would not be motivated to cook papaya fruits for such an extended period of time because it is well known in the art that papain, which is present in the papaya fruit and responsible for its beneficial effects, is temperature sensitive. An extended heating period would expectedly destroy these beneficial effects. Therefore, the short period of exposure of high temperature for preparing a papaya product as disclosed in Wolff should be more appropriately viewed as Wolff’s recognition of heat sensitivity of papaya and an effort to limit the supposedly negative effects caused by exposure to high temperature. Above all, there is simply no suggestion or reasonable expectation of success for a method of claim 1.

Further, objective evidence is sufficient in this case to rebut any *prima facie* finding of obviousness. It is surprising that the product obtained by the method according to the present invention exhibits superior therapeutic effects that are ordinarily attributed to papain to products obtained by other methods. This position is supported by the attached Rule 132 Declaration by Dr. Wutschitz, and a clinical study enclosed therewith, which evaluates the efficacy of a papaya puree preparation obtained according to the methods of the present application as compared with that of a product obtained by a customary method known in the art. Dr. Wutschitz's study clearly shows that the papaya preparation according to the present application has a surprising and significant efficacy in treating a gastroenterological condition as opposed to a papaya pulp product obtained without being subjected to the extended period of cooking required in claim 1.

Based on the above reasons, Applicant submits that independent claim 1 is not obvious over Wolff. As all the other claims under this rejection depend from claim 1, they are not obvious over Wolff for at least the same reasons.

(B) Rejections of claim 4 over Wolff in view of U.S. Patent No. 5,840,356 to Swensen ("Swensen") (Office Action, pages 6-7).

The Examiner asserts that Wolff teaches as above, and further alleges that Swensen teaches the additional limitation of claim 4 (relative to claim 1) of adding citric acid to lead to the pH range of the puree preparation from 3.5 to 5.

Applicant disagrees. The relevance of Wolff is discussed above and incorporated herein. Further, Swensen does not cure the deficiency of Wolff regarding the cooking and cooling steps. Therefore, independent claim 1 cannot be obvious over Wolff in view of Swensen. As claim 4 depends from claim 1, it is not obvious for at least the same reasons.

(C) Rejections of claims 8-14 over Wolff in view of Dawson, Chandalia, and Imao (Office Action, pages 7-8).

The Examiner rejects claims 8-14 based on various teachings in *The Medicinal Properties of Papaya* (by Emma Dawson, "Dawson"), *Beneficial Effects of High Dietary Fiber Intake in Patients with Type 2 Diabetes* (by Chandalia et al., "Chandalia"), and *Free Radical Scavenging Activity of Fermented Papaya Preparation and Its Effect On Lipid Peroxide Level and Superoxide Dismutase Activity in Iron-Induced Epileptic Foci of Rats* (by Katsuki Imao et al., "Imao").

Applicant resubmits the arguments as presented above regarding the teachings of Wolff, and further points to MPEP 2116.01, which cautions that proper claim construction requires treating language in a process claim which recites the making or using of a nonobvious product as a material limitation. Since the papaya puree product prepared according to the present application is not obvious over Wolff, the methods of use of the product should not be deemed as obvious. Further, as evidenced in the attached Rule 132 Declaration by Dr. Wutschitz and the results from the clinical study performed by Dr. Wutschitz, the papaya preparation according to the present application has a surprising and significant efficacy in treating a gastroenterological condition as opposed to a papaya pulp product obtained without being subjected to the extended period of cooking, as required in these rejected claims. Therefore, claims 8-14 are not obvious over the cited art.

(D) Rejections of claims 17-20 over Wolff in view of JP 08056562 to Nakayama  
("Nakayama") (Office Action, pages 8-10).

Claims 17-20 depend from claim 15, which in turn depends from claim 1. Since claim 1 has been shown as not being obvious over Wolff as discussed above, and Nakayama does not cure the deficiency of Wolff (the Examiner's reliance on Nakayama only pertains to Nakayama's teaching with regard to the sugar content of a papaya product), claim 1 cannot be rendered obvious by the combination of Wolff and Nakayama.

Based on the foregoing, Applicant respectfully requests that all rejections under 35 U.S.C. 103(a) be withdrawn.

**IV. Conclusion**

In view of the above amendments and remarks, it is respectfully requested that the application be reconsidered and that all pending claims be allowed and the case passed to issue. If any of the pending claims are not deemed allowable, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below.

If any fees are due in connection with this response or any overpayment has been made, the Director is hereby authorized to charge such fees and to credit any overpayment to Deposit Account No. 02-4377.

Dated: September 23, 2009

Respectfully submitted,

  
Chang Sik Kim  
PTO Registration No. 63,335

Baker Botts L.L.P.  
30 Rockefeller Plaza  
New York, NY 10112

*Attorney for Applicant*  
(212) 408-2500